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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 01/27/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

09/940,287

Applicant(s)

BARDY ET AL.

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears n th cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-263 is/are pending in the application.
- 4a) Of the above claim(s) 13,14,71,72,129,130,187,188 and 232-263 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 15,20,29-35,73,78,87-93,131,136,145-151,189,194 and 203-209 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims rejected are 1-12,16-19,21-28,36-70,74-77,79-86,94-128,132-135,137-144,152-186,190-193,195-202 and 210-232.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Invention I and the species involving a tube-shaped appendage (claims 1-12, 15-70, 73-128, 131-186 and 189-232) in Paper No. 7 is acknowledged.

***Specification***

2. The disclosure is objected to because of the following informalities: the status of the cross-referenced applications referred to on page 1 should be updated; numerous errors appear in the referencing of drawing elements –careful perusal is suggested.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17 and 137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Reference to “the bounded region” in claim 17 lacks antecedent basis. It is not clear if the applicant is attempting to positively recite such a region and it is not clear exactly what such a region entails. This error should be corrected wherever it appears in the lengthy claim set.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 7-12, 16, 17, 22-24, 28, 36-42, 44-48, 54-56, 59-63, 65-70, 74, 75, 80-82, 86, 94-100, 102-106, 112-114, 117-121, 123-128, 132, 133, 138-140, 144, 152-

158, 160-164 and 170-172 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilman (Pat. No. 4,270,549).

Regarding claim 1 and claims with similar limitations, Heilman shows a lead electrode assembly comprising an electrode 12 and a pocket 44 coupled to the electrode for positioning the lead electrode assembly (note col. 6, lines 43-46). While the preamble was considered, the language "...for subcutaneous implantation..." was deemed to be merely a statement of intended use for the electrode assembly lacking any specific structural recitation in the body of the claim limiting the apparatus to such use.

Concerning claims 2 and 3 and claims with similar limitations, the examiner considers the region of the pocket defined by the stitching 36 and distal end of the pocket (i.e., the end of the pocket furthest from the opening) to constitute a bounded contiguous region.

With reference to claim 4 and claims with similar limitations, the region of the pocket wrapped around element 14 at the distal end of the pocket is considered to have a curved shape as can be seen in cross-section in Fig. 2.

Regarding claim 8 and claims with similar limitations, the examiner considers Silastic to comprise silicone and mixtures thereof.

Concerning claim 11 and claims with similar limitations, the examiner considers the word "rigid" to be a relative term and thus interprets the sandwiched Dacron reinforced layers 14 and 16 to be rigid backing layers.

Regarding claim 12 and claims with similar limitations, the examiner considers the insertion tool 60 to represent an appendage positioned between the electrode and the pocket.

Regarding claim 42 and claims with similar limitations, note col. 4, lines 33-37. The ranges listed include surface areas between 100 square millimeters and 2000 square millimeters.

Concerning claim 55 and claims with similar limitations, note the discussion of the clip discussed in col. 6, lines 20-24. The weld material itself (e.g., solder) can also be considered a lead fastener.

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7. Claims 1, 7, 9, 10, 16-19, 21, 22, 25-27, 40, 41, 44-48, 54-57, 59, 65, 67, 68, 74-77, 79, 80, 83-85, 98, 99, 102-106, 112-115, 117, 123, 125, 126, 132-135, 137, 138, 141-143, 156, 157, 160-164, 170-173, 175, 181, 183, 184, 190-193, 195, 196, 199-201, 214, 215, 218-222 and 228-231 are rejected under 35 U.S.C. 102(b) as being anticipated by Strahwald et al. (Pat. No. 4,354,509).

Regarding claim 1 and claims with similar limitations, Strahwald et al. disclose a lead electrode comprising an electrode (the conductive surface comprising elements 13-15) and a pocket 1 for positioning the lead electrode assembly (note col. 2, lines 37-41). Once again the recitation "...for subcutaneous implantation..." in the preamble was considered, but deemed an intended use and thus insufficient to saliently distinguish over the apparatus defined by Strahwald et al.. Furthermore, the term "coupled" was considered broad enough to reasonably include systems such as shown by Strahwald et al. which show the electrode joined to the pocket by receptive association.

Regarding claim 17 and claims with similar limitations, one can consider the "bonded region" to be that region of the pocket that is stitched.

Regarding claim 25 and claims with similar limitations, the examiner considers the outline of the pocket to show a curved shape.

Concerning claim 57 and claims with similar limitations, Fig. 4 shows an electrode length just less than the length of the pocket.

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6, 25-27, 43, 49-53, 64, 83-85, 101, 107-111, 122, 141-143, 159, 165-169, 175-186, 190, 191, 196-202 and 210-230 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman (Pat. No. 4,270,549).

In regards to claim 6 and claims with similar limitations, although the bounded region of Heilman does not form part of the circumference of a circle, lacking any criticality, those of ordinary skill in the art would have considered the exact stitching pattern for forming the pocket to be a matter of obvious design dependent upon the particular manufacturing process used, the shape of the electrode and the particular configuration of the mating positioning tool intended to be inserted into the pocket. For instance, although Heilman employs a rectangular shaped electrode, one can easily extrapolate how the bounded region would look if the electrode had a circular or oval shape (i.e., the stitching would necessarily follow the contour of the circular electrode).

Similar comments apply to claims 25-27.

The examiner wishes to point out that the previous Office Action did not require election of various species (the species defined by claims 25-27 included) that were not considered to be patentably distinct. The applicant had the opportunity to traverse the restriction requirement and declare on record that the various species discussed by the examiner were patentably distinct, but did not timely do so. The discovery of one species (a rectangular shaped pocket) is therefore considered evidence of the obviousness of the other patentably indistinct species (e.g., a curved pocket, a triangular shaped pocket, etc.).

Comments related to those given above apply to claim 43 as well.

Regarding claim 49 and claims with similar limitations, Heilman does not bother to disclose lead length. Considering both the applicant and Heilman are concerned with providing cardioverting/defibrillating energy to the heart via an implanted lead system, it would logically follow that both systems would require substantially similar lead lengths to accommodate the body dimensions of the typical recipient. To employ lead lengths of between 5 and 52 cm to account for changes in body size would have therefore been considered a matter of obvious design with the exact length dictated by the individual under treatment. Like comments apply to claims 50 and 51.

Regarding claims 52 and 53 and claims with similar limitations, the applicant appears to be defining the invention in terms of non-elements of the invention. The applicant is not claiming a set of leads with a plurality of preset lengths varying by

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approximately 10 cm –simply that the lead used is one of a plurality of preset lengths. Whether a lead falls into this category is simply a matter of how many different leads a manufacturer may produce.

Regarding claim 175, comments parallel to those found in the rejection of independent claims 1, 60 and 117 apply here as well. Although Heilman does not explicitly refer to a housing, those of ordinary skill in the art would have considered the provision of a housing to contain the electrical circuitry of the defibrillator to be blatantly obvious. Such means are an absolute necessity for the safety of the patient and for the protection of the device components. The examiner additionally takes Official Notice to this effect.

10. Claims 58, 116, 174 and 232 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Strahwald et al. (Pat. No. 4,354,509).

Regarding the above claim set, although Strahwald et al. do not show an electrode length equal to the length of the pocket, for all practical purposes the pocket and the electrode shown are of substantially similar length. Whether the pocket length and the electrode length are equal may simply depend on what one defines as an electrode length (e.g., one might define the electrode length to be the distance measured along a diagonal line from one conductive pad tip to the other). In any event, the applicant gives no criticality to the exact dimensioning of the pocket with relation to the pad. It would appear that a pocket of equal length to the length of an electrode would work just as well in the system of Strahwald et al.. Given the lack of criticality and lacking any teaching away from such an arrangement by Strahwald et al., those of ordinary skill in the art would have considered the exact relative lengths to be a matter of obvious design.

#### ***Allowable Subject Matter***

11. Claims 15, 29-35, 73, 78, 87-93, 131, 136, 145-151, 189, 194 and 203-209 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



The use of a tube-shaped appendage is not taught by prior artisans, nor is there a teaching for providing a molded cover coupled to the electrode in addition to the recited pocket.


**Conclusion**

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS  
January 13, 2004

  
KENNEDY SCHAETZLE  
PRIMARY EXAMINER